

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION**

FILED

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CLERK OF DISTRICT COURT
ALEXANDRIA, VIRGINIA

ACTELION PHARMACEUTICALS LTD.
Gewerbestrasse 16
CH - 4123 Allschwil
Switzerland,

Plaintiff,

v.

HON. MICHELLE K. LEE
Under Secretary of Commerce for Intellectual
Property and Director of the United States Patent
and Trademark Office
P.O. Box 1450, Alexandria, VA 22313
401 Dulany Street, Alexandria, VA 22314

Office of the General Counsel
United States Patent and Trademark Office
P.O. Box 15667, Arlington, VA 22215
Madison Building East, Room 10B20
600 Dulaney Street, Alexandria, VA 22314,

Defendant.

Case No.

1:16-CV-304
(LO/TCB)

COMPLAINT

Plaintiff Actelion Pharmaceuticals, Ltd. ("Actelion"), by its undersigned attorneys, for its Complaint against the Honorable Michelle K. Lee ("Defendant"), respectfully states as follows:

NATURE OF ACTION

1. This is an action by the owner and assignee of United States Patent No. 8,658,675 ("the '675 Patent"), pursuant to 35 U.S.C. § 154 (b)(4)(A), 5 U.S.C. §§ 701-706, and the Fifth Amendment of the Constitution of the United States of America, seeking judgment that the patent term adjustment for the '675 Patent be changed from 40 days to 45 days.

2. This action arises under 35 U.S.C. § 154 (b)(4)(A), the Administrative Procedures Act, 5 U.S.C. §§ 701-706, and the Fifth Amendment of the Constitution of the United States of America.

THE PARTIES

3. Plaintiff Actelion Pharmaceuticals Ltd., (hereinafter “Actelion”) is a public limited company organized under the laws of Switzerland, having a principal place of business at Gewerbestrasse 16, CH - 4123 Allschwil, Switzerland.

4. Defendant Michelle K. Lee is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (“PTO”), acting in her official capacity. The Director is the head of the agency, charged by statute with providing management supervision for the PTO and for the issuance of patents. The Director is the official responsible for determining the period of patent term adjustment under 35 U.S.C. § 154(b)(3).

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action and is authorized to issue the relief sought pursuant to 28 U.S.C §§ 1331, 1338(a) and 1361; 35 U.S.C. § 154(b)(4)(A); 28 U.S.C. § 2201; and 5 U.S.C. § 701-706.

6. Venue is proper in this district by virtue of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 9, 125 Stat. 316 (2011) and pursuant to 35 U.S.C. § 154(b)(4)(A).

7. This action is timely filed in accordance with 35 U.S.C. § 154(b)(4)(A).

ALLEGATIONS COMMON TO ALL COUNTS

8. Martin Bolli, Cyrille Lescop, Boris Mathys, Keith Morrison, Claus Mueller, Oliver Nayler, and Beat Steiner are the inventors of the invention claimed in the U.S. Patent Application Serial No. 13/383,619 (“the ‘619 Application”) entitled “Pyridin-4-yl Derivatives,” filed on

January 12, 2012, which issued as the '675 Patent on February 25, 2014. A true and correct copy of the '675 patent is attached hereto as Exhibit A.

9. Plaintiff Actelion is the owner and assignee of all right, title and interest in the '675 Patent, as evidenced by the assignment document recorded with the PTO at Reel/Frame 027677/0559 on February 9, 2012, in which the inventors assigned all rights, title and interest to Actelion, which is the real party in interest in this case.

10. Section 154 of Title 35 of the United States Code requires that the Director of the PTO grant a patent term adjustment in accordance with the provisions of Section 154(b)(1) PATENT TERM GUARANTEES, which includes: (A) GUARANTEE OF PROMPT PATENT AND TRADEMARK OFFICE RESPONSES and (B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY, and are offset by: (C) REDUCTION OF PERIOD OF ADJUSTMENT.

11. Section 154(b)(1)(A)(i)(II) of Title 35 of the United States Code provides that the term of a patent shall be extended, subject to certain limitations, if issue of the patent is delayed due to failure of the PTO to provide at least one of the notifications under section 132 or a notice of allowance under section 151 of Title 35 no later than 14 months after the date of commencement of the national stage under section 371 in an international application. This is referred to as "A-delay."

12. The '619 application was a national stage entry under 35 U.S.C. § 371 of International Patent Application PCT/IB2010/053224, filed on July 15, 2010, which claims priority to International Patent Application PCT/IB2009/053089, filed on July 16, 2009. The earliest effective priority date for the '619 application is July 16, 2009.

13. Pursuant to 37 C.F.R. § 1.703(a)(1), as amended by the AIA Technical Corrections Act, Pub. L. No. 112-274, 126 Stat. 2456 (January 14, 2013) (codified in scattered sections of 35 U.S.C.), the 14-month period calculated pursuant to 35 U.S.C. § 154(b)(1)(A)(i)(II) begins on the date of commencement of the national stage of an international application.

14. 35 U.S.C. § 371(b) provides that “[s]ubject to subsection (f) of this section, the national stage *shall commence* with the expiration of the applicable time limit” under PCT Article 22(1). (emphasis added)

15. PCT Article 22(1) provides that “[t]he applicant shall furnish a copy of the international application . . . and a translation thereof (as prescribed), and pay the national fee (if any), to each designated Office not later than at the expiration of 30 months from the priority date.”

16. 35 U.S.C. § 371(f) provides that “[a]t the express request of the applicant, the national stage of processing may be commenced at any time at which the application is in order for such purpose and the applicable requirements of subsection (c) of this section have been complied with.”

17. Patent Term Adjustment is calculated by taking the sum of A-delay, B-delay and C-delay, and subtracting therefrom both overlap and applicant delay. It is undisputed that B-delay, C-delay, Applicant delay and overlap are all zero. Therefore, in this case, the total amount of Patent Term Adjustment is the amount of A-delay.

18. It is undisputed that the first notification under 35 U.S.C. § 132, which stops the running of the A-delay clock, was the mailing of a Restriction Requirement on April 26, 2013. The Parties’ only dispute is when the A-delay clock began running.

19. It is undisputed that the earliest effective priority date for the ‘619 application is July 16, 2009. The date that is 30-months from this date is Monday, January 16, 2012.

20. The PTO originally calculated a Patent Term Adjustment (“PTA”) of 41 days, based on a national stage commencement date of Monday, January 16, 2012. Pursuant to 35 U.S.C. § 154(b)(1)(A)(i)(II), this date sets the 14-month deadline for the mailing of a first notification under 35 U.S.C. § 132 as March 16, 2013. As the PTO mailed the first notification on April 26, 2013, this results in an A-delay calculation of 41 days, and therefore, 41 days of PTA.

21. Plaintiff subsequently filed a timely and proper Request for Recalculation of Patent Term Adjustment in View of the AIA Technical Corrections Act (provided by the Optional Procedure

for Seeking a Revised Patent Term Adjustment Calculation under the AIA Technical Corrections Act, 79 Fed. Reg. 27755, May 15, 2014).

22. In response to said Request, the PTO issued a Recalculation of Patent Term Adjustment that calculated the A-delay to be only 40 days. Thus, the PTA became 40 days. This change resulted from the PTO reconsidering the national stage commencement date as Tuesday, January 17, 2012, because Monday, January 16, was a Federal Holiday (Martin Luther King Day).

23. Plaintiff subsequently filed a timely and proper Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. § 1.705(b) on November 25, 2014.

24. In response to the Request for Reconsideration of Patent Term Adjustment, the PTO issued a final decision denying the request for reconsideration on September 21, 2015. A true copy of the September 21, 2015 Final Decision on PTA is attached hereto as Exhibit C. This decision affirmed the finding that the PTA should be 40 days. This decision was indicated to be “the Director’s decision on the applicant’s request for reconsideration for purposes of seeking judicial review under 35 U.S.C. § 154(b)(4).” (Ex. C at 1.)

25. The PTO erred in determining the date of national stage commencement. Under the clear and unambiguous language of 35 U.S.C. § 371(f), at “the express request of the applicant” the national stage may commence at any time at which the requirements of 371(c) have been satisfied.

26. In the Final Decision on PTA of September 21, 2015, the PTO determined that “patentees’ [*sic*] failed to make an express request to begin national examination” because there was no “clear, definite, explicit, plain, direct, unmistakable request to begin national examination procedures.” (Ex. C at 3.) Moreover, the PTO ruled that “patentees [*sic*] request was at best dubious, ambiguous and left to inference.” (*Id.*)

27. Plaintiff met all of the requirements for national stage entry under 35 U.S.C. § 371(c) on the filing date of January 12, 2012.

28. Filed concurrently with the '619 application on January 12, 2012, was a preliminary amendment. A true and correct copy of the preliminary amendment filed on January 12, 2012, is attached hereto as Exhibit B. In the preliminary amendment was the following express request: "Applicant earnestly solicits early examination and allowance of these claims." (Ex. B at 9.) There could be no clearer, more definite, more explicit, and less unambiguous request that examination begin than this statement. Therefore, Applicants made an "express request" for national stage processing on January 12, 2012, and so this date should be considered the date of national stage commencement. A-delay, and by extension PTA, should thus be calculated to be 45 days.

29. While an "express request" for national stage processing *may* be made by checking off Box 3 of PTO Form 1390 ("Transmittal Letter to the United States Designated/Elected Office (DO/EO) Concerning a Submission Under 35 U.S.C. 371"), there is no provision in Title 35 of the United States Code, or in Title 37 of the Code of Federal Regulations, nor in the Manual of Patent Examining Procedure which *mandates* that an express request under 35 U.S.C. § 371(f) *must* be made by checking Box 3 of PTO Form 1390.

30. The U.S. PTO website provides that "[t]he USPTO provides patent forms to the public to use in certain situations, but, *in almost all situations*, the USPTO does not require use of a form, or even provide a form, to submit the information required. . . . Any submission that meets all requirements of the Patent Laws, Rules and Orders and Notices . . . will be accepted" (emphasis added). ("Forms", under the heading "IMPORTANT NOTICES AND REMINDERS REGARDING USE OF PATENT FORMS", <http://www.uspto.gov/patent/forms/forms>, retrieved 11/19/2015). The PTO's own guidance regarding use of its forms, as well as the plain language of 35 U.S.C. § 371(f), which contains no such requirement, firmly stand against the PTO's arbitrary decision in this case that checking Box 3 of Form 1390 is the *only* acceptable way to expressly request national stage processing.

31. Under the PTO's interpretation of the rules, a patentee stands to lose Patent Term Adjustment based on a decision made at the time of filing an application that could not have been predicted to have an impact on Patent Term Adjustment. Thus, the PTO would have this Court find that if Plaintiff did not expressly request early national stage processing, they should

lose Patent Term Adjustment. Yet, under the laws governing Patent Term Adjustment in effect at the time that Plaintiff filed the present application, whether an express request for national stage entry was made had no influence on Patent Term Adjustment. At the time, A-delay under the PTA statute was governed by the date upon which the requirements of 35 U.S.C. § 371(c) were met, not by the date that the national state commenced. The '619 application fulfilled the requirements of section 371 on the filing date, January 12, 2012. Based on the law at the time of Plaintiff's filing date (and the time of the mailing of the restriction requirement), A-delay would have been calculated based on the date 14 months from January 12, 2012, which would have afforded Plaintiff 45 days of A-delay. It would thus be fundamentally unfair to interpret the rules in such a manner that a patentee loses PTA for a decision made during application filing that at the time would have had no impact on PTA.

32. Moreover, at a minimum, and in the alternative, even if the PTO had correctly found that that the Applicants did not make an "express request" for national stage processing on January 12, 2012, so that that date would be considered the date of national stage commencement, the PTO should at least have considered that the national stage commenced on the date which was 30-months from the earliest priority date of the application, January 16, 2012.

33. The PTO does not have the authority to set aside the plain language of the statute and decide that the 30-month national stage commencement date rolls over to the next business day when the 30-month date falls on a weekend or national holiday. By the clear and express language of 35 U.S.C. § 371(b), "the national stage *shall commence* with the expiration the applicable time limit under article 22 (1) . . ."; *i.e.*, "not later than at the expiration of 30 months from the priority date", as provided in PCT Article 22(1).

34. PCT Article 22(3) provides that national law may, for performing the acts referred to in Article 22(1) or (2), fix time limits which expire later than the time limit provided for in those paragraphs. Significantly, in defining national stage commencement in 35 U.S.C. § 371(b), Congress chose NOT to take account of such extensions of time or make reference to PCT Article 22(3). Various provisions of law and regulation, such as 35 U.S.C. § 21(b), 37 C.F.R. §1.7, or PCT Rule 80.5, provide patent applicants with a brief extension of time *to take an*

action if the deadline falls on a weekend or holiday. Such extensions of time apply to a time for taking action; they do not purport to change the plain meaning of “not later than at the expiration of 30 months from the priority date”. There is no statutory authority for the PTO to reset the date of national stage commencement based on the day of the week on which that date falls.

35. Therefore, at a minimum, the PTO should at least have considered that the national stage commenced on the date which was 30-months from the earliest priority date of the application, January 16, 2012. A-delay, and by extension PTA, should thus be considered, at a minimum, to be 41 days.

36. Under applicable law, including 35 U.S.C. §154(b) and 35 U.S.C. §254, PTO has the authority and the obligation to correct the improper calculation of PTA in this case, and despite the Applicant’s timely requests, has failed and refused to do so.

COUNT 1 - Action for Adjustment of Patent Term under 35 U.S.C. § 154(b)

37. The allegations of paragraphs 1-36 are incorporated in this claim for relief as if fully set forth herein.

38. United States Patent No. 8,658,675, assigned to Plaintiff, issued on February 24, 2014, and the Defendant, by the September 21, 2015 Final Decision on PTA, granted a Patent Term Adjustment of 40 days.

39. Defendant’s Petition Decision dated September 21, 2015, is a final agency decision within the meaning of 5 U.S.C. § 704 for the purposes of seeking judicial review.

40. The Defendant’s granted patent term adjustment of 40 days includes a period of “A Delay” of 40 days, a period of “B delay” of zero days, a period of “C delay” of zero days, a period of “Applicant’s delay” of zero days, and zero overlapping days of delay.

41. Applicants made an “express request” for national stage processing on January 12, 2012, and this date should be considered the date of national stage commencement. A-delay, and by extension PTA, should thus be calculated to be 45 days. The correct patent term adjustment for the ‘675 patent is properly determined to be 45 days ((“A Delay”: 45 + “B Delay”: 0 + “C delay”: 0) – (Overlapping days: 0) – (“Applicant’s delay”: 0) = 45 days).

42. In the alternative, the PTO should at least have considered that the national stage commenced on the date which was 30-months from the earliest priority date of the application, January 16, 2012. A-delay, and by extension PTA, should thus be considered, at a minimum, to be 41 days. The correct patent term adjustment for the ‘675 patent in this case would properly determined to be 41 days ((“A Delay”: 41 + “B Delay”: 0 + “C delay”: 0) – (Overlapping days: 0) – (“Applicant’s delay”: 0) = 41 days).

43. The ‘675 Patent is not subject to a terminal disclaimer, so the provisions of 35 U.S.C. § 154(b)(2)(B) do not apply and the full 45 days of patent term adjustment, or in the alternative 41 days, should be granted.

44. The Defendant’s determination that the ‘675 Patent is entitled to only 40 days of patent term adjustment is arbitrary, capricious, an abuse of discretion, clear error or otherwise not in accordance with law and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

45. Plaintiff is thus entitled to additional patent term for the ‘675 patent, such that the 40 days of PTA granted by the PTO should be changed to 45 days, or at a minimum to 41 days.

COUNT 2 – Administrative Procedures Act

46. The allegations of paragraphs 1 – 45 are incorporated in this claim for relief as if fully set forth herein.

47. The United States Patent and Trademark Office (“PTO”) is an agency of the United States government. Judicial review of PTO action is not precluded and is expressly permitted by

statute. The calculation of patent term is determined by statute and is not committed to the PTO's discretion.

48. Defendant's determination of the date of national stage commencement, as required by 35 U.S.C. § 154(b)(1)(A)(i), and under the provisions of 35 U.S.C. § 371(b) and/or 35 U.S.C. § 371(f) is arbitrary and capricious, inconsistent with the PTO's own rules, and has resulted in the improper calculation "A-delay" for the '675 patent.

49. Defendant's conclusion that Plaintiff's express request for national stage processing was at best dubious, ambiguous and left to inference is arbitrary and capricious and is an abuse of discretion, or is otherwise not in accordance with the law within the meaning of 5 U.S.C. § 706(2)(A).

50. Defendant's determination that national stage commencement cannot occur on a weekend or Federal holiday when the 30-month period under PCT Article 22(1) falls on such a date, even when the patent applicant has fulfilled the requirements for national stage commencement *on or before such date*, is arbitrary and capricious and is an abuse of discretion, or is otherwise not in accordance with the law within the meaning of 5 U.S.C. § 706(2)(A).

51. Plaintiff, as assignee of the '675 patent, has suffered legal wrong because of the PTO's actions in miscalculating the term of the '675 patent and failing to provide an adequate remedy for correction of such miscalculation. Plaintiff is and has been adversely affected and aggrieved by such actions. There is no adequate remedy available to Plaintiff, either administratively through the PTO or in any other forum, other than this Court.

52. The conduct of the PTO in miscalculating the term of the '675 patent and then failing and refusing to correct such miscalculation is

- (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
- (B) contrary to constitutional right, power, privilege, or immunity;
- (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
- (D) without observance of procedure required by law;

(E) unsupported by substantial evidence; and

(F) unwarranted by the facts.

53. Plaintiff is entitled to additional patent term for the '675 patent, such that the 40 days of PTA granted by the PTO should be changed to 45 days, or at a minimum to 41 days.

COUNT 3 – United States Constitution

54. The allegations of paragraphs 1-53 are incorporated in this claim for relief as if fully set forth herein.

55. The Fifth Amendment to the Constitution of the United States provides in relevant part that no person shall be “deprived of . . . property, without due process of law; nor shall private property be taken for public use, without just compensation.”

56. Plaintiff enjoys a substantial and cognizable private property right in the full and complete term of the '675 patent.

57. Defendant's improper determination of the Patent Term Adjustment accorded to the '675 patent constitutes a permanent deprivation of Plaintiff's patent term and rights to which Plaintiff is entitled under 35 U.S.C. § 154(b).

58. The Defendant's failure to accord the statutorily mandated term to the '675 patent, effectively dedicating a portion of the term of that patent to the public, constitutes an arbitrary and unjustified deprivation and taking of a property right established by Article I, Section 8, of the United States Constitution and secured by the Fifth Amendment of the United States Constitution, without just compensation.

59. Plaintiff is entitled to additional patent term for the '675 patent, such that the 40 days of PTA granted by the PTO should be changed to 45 days, or at a minimum to 41 days.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Actelion Pharmaceuticals Ltd., respectfully prays that this Court:

(A) Issue an Order correcting the period of the patent term adjustment for the '675 Patent and setting aside the prior determination of the PTO;

(B) Issue an Order compelling the Defendant forthwith to correct the period of the patent term adjustment for the '675 Patent, and compelling the Director to extend the term of the '675 Patent to reflect the correct patent term adjustment;

(C) Issue an award of the Plaintiff's reasonable attorneys' fees, expenses and costs of suit, in accordance with 28 U.S.C. § 2412, 35 U.S.C. § 285, and other applicable law; and

(D) Grant such other and further relief as the nature of this case may admit or require and as may be just and equitable.

Dated: March 18, 2016

Respectfully submitted,



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